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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,728	08/10/2001	Peter Geistlich	1194-179	5552

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 01/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/925,728

Applicant(s)

GEISTLICH ET AL. MF

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 August 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,4,5,12,15,16,21,22 are rejected under 35 U.S.C. 102(e) as being anticipated by Vibe-Hansen et al. (5759190). Vibe-Hansen et al. disclose a method of promoting regeneration of surface cartilage by applying a collagen membrane patch charged with chondrocytes to a joint area, such that the patch has a single barrier layer (col. 2, lines 17-34). Vibe-Hansen et al. disclose the collagen membrane has a matrix layer of collagen II, col. 8, lines 43-45. The patch is fixed over the area either by adhesively bonding or suturing the patch to cartilage surrounding the area treated, col. 7, lines 14-18. The patch has a barrier layer with a smooth or dense face and a fibrous or porous face with the matrix adhered thereto, col. 7, lines 57-67. Vibe-Hansen also discloses the membrane as having a barrier layer or dense surface made of collagen I and III taken from pigs, col. 7, lines 7-13.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2,3,18-20,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vibe-Hansen et al. '190 in view of Stone et al. (5624463). Vibe-Hansen et al. is explained supra. However, Vibe-Hansen does not disclose the matrix layer being impregnated with a glycosaminoglycan. Stone et al. teach the use of a glycosaminoglycan, such as dermatan sulphate in the matrix layer that is crosslinked and forms a covering for a cartilage defect, col. 3, lines 8,9,17,18,30-35. Stone also teaches that collagen II is a useful matrix material, col. 6, lines 3,4,12,13,36-39. The type II collagen is natural cartilage, col. 7, lines 53,54,62,63. The collagen II can be obtained from pigs, col. 8, lines 62,63. It would have been obvious to one of ordinary skill in the art to impregnate the matrix with a glycosaminoglycan and use collagen II that is natural taken from pigs as taught by Stone et al. in the matrix of Vibe-Hansen et al. in order to strengthen the matrix and aid in the crosslinking by having the glycosaminoglycan. Natural cartilage is easily obtained from animals and is a good source of collagen II that structurally permits good crosslinking capabilities.

Claims 6,7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vibe-Hansen et al. '190 in view of Geistlich et al. (WO 95/18638). Vibe-Hansen et al. is explained supra. However, Vibe-Hansen does not disclose the membrane carrying the

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pharmaceutical active substance Taurolidine. Geistlich et al. teach that taurolidine can be used with the membrane for chemotherapeutic purposes, page 11, lines 7-10. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with Taurolidine as taught by Geistlich et al. in the membrane of Vibe-Hansen in order to reduce neoplasia.

Claims 8,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vibe-Hansen et al. '190 in view of Sonis (WO 90/13302). Vibe-Hansen et al. is explained supra. However, Vibe-Hansen do not disclose the membrane carrying pharmaceutically active substances, such as BMPs. Sonis teaches that BMPs can be used with membranes for tissue regeneration, page 10, lines 22-31. Table II (page 28) show numerous agents, i.e. PDGF or PTH. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with a pharmaceutically active substance as taught by Sonis in the membrane of Vibe-Hansen in order to enhance the capabilities of the tissue regeneration process and allow for controlled release of the substances.

Claims 10,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vibe-Hansen et al. '190 in view of Caplan et al. (5197985). Vibe-Hansen et al. is explained supra. However, Vibe-Hansen do not disclose the use of stem cells or stromal cells incorporated in the membrane. Caplan et al. teach that mesenchymal stem cells can be incorporated into carriers or membranes for tissue regeneration, col. 2, lines 6-11,27-34. Caplan also teaches that the stem cells are capable of determining which connective tissue to regenerate, i.e. cartilage, col. 3, lines 20-24,35-45. The cells

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and carrier is used to repair cartilage of a joint, col. 16, lines 40-53. Caplan additionally teaches that stromal cells from bone marrow can be harvested for use, col. 15, lines 25-28,39-49. It would have been obvious to one of ordinary skill in the art to impregnate the membrane with stem or stromal cells as taught by Caplan et al. in the membrane of Vibe-Hansen in order to provide enhanced osteogenic activity.

Claims 13,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vibe-Hansen et al. '190 in view of Geistlich et al. (5573771). Vibe-Hansen et al. is explained supra. However, Vibe-Hansen et al. do not disclose the use of a bone mineral implanted in the region of the bone injury. Geistlich et al. teach that a bone mineral is useful for implanting in a bone cavity for remodeling, col. 2, lines 52-62. Geistlich also teaches the bone mineral improves strength of the bone at the defect and these implants can be charged with bone cells, col. 3, lines 10-15,53-56. It would have been obvious to one of ordinary skill in the art to use a bone mineral as taught by Geistlich et al. charged with the chondrocytes in the membrane of Vibe-Hansen in order strengthen the area of the defect and provide a more natural environment for the cells.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vibe-Hansen et al. '190 in view of Seid (5254133). Vibe-Hansen et al. is explained supra. However, Vibe-Hansen et al. do not disclose the use of two barrier layers to sandwich the matrix. Seid teaches (Fig. 13) that a coating **76** forms a barrier layer that sandwiches an inner component of the tissue patch. Seid also teaches the coating prevents tissue formation, col. 9, lines 3-8. It would have been obvious to one of

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ordinary skill in the art to use a barrier layer on both sides of the matrix of Vibe-Hansen using the teaching of Seid to inhibit tissue formation prematurely.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5,12,23,24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1,9-11,13-15,18,19 of U.S. Patent No. 6352558. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to regeneration of surface cartilage of a joint and involve the use of a collagen membrane as a patch placed over an area to be treated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-

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5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738
1/10/02


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